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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT PAPER NUMBER

1753

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,470

Applicant(s)

NAKAMURA, SHIN

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

1. Claim 6 is objected to because of the following informality: in line 10 "an" should be deleted . Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Li et al. (WO 00/54041 A1) ("Li").

Addressing claim 1, Li discloses a microfluidic device for analyzing a sample (abstract), comprising

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a base member (Figure 1A:(20) or Figure 2A:118);

a separating channel (Figure 1A: ((22), page 7:15-16) *or* Figure 2A: the channel in chip 118 that extends from 176, which corresponds to 22 in Figure 1A) formed in the base member;

a sample-injecting portion (Figure 1A:(26) or Figure 2A:(130)) formed at one end of the separating channel;

a sample quantity control channel (Figure 1A:((50), page 9:3-8)) or Figure 2A: (134) or (130), page 13:4-5) formed in the base member and branching from the separating channel, the sample quantity channel having a volume for the sample to be introduced (page 13:4-5);

a first opening and closing mechanism (Figure 1A:(60) or Figure 2A: (172)) disposed at the other end of the separating channel; and

a second opening and closing mechanism (Figure 1A: (52) or Figure 2A: (114) or (166)) disposed at one end of the sample quantity control channel away from the separating channel.

Addressing claim 2, for the additional limitation of this claim note element 170 in the embodiment of Figure 2A.

Addressing claim 4, for the additional limitations of this claim see Figures 1A and 2A.

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Addressing claim 5, for the additional limitation of this claim see Figures 1C and 2C.

Addressing claim 6, Li discloses an analyzing method for analyzing a sample, comprising the steps of

filling a migration buffer in a separating channel (page 8:9-26; page 9:9-18; page 13:1-4; and page 13:12-13);

introducing the sample into the separating channel from a sample injecting portion for an amount corresponding to a volume of a sample quantity control channel branching from the separating channel (page 9:3-8; page 13:1-12; and page 14:11-22); and

applying a voltage between the sample injecting portion and an end of the separating channel away from the sample-injecting portion so that the sample is separated by electrophoresis (page 8:1-8; page 9:17-18; page 12:13-19; and page 14:11-22).

Note:

separation channel - (Figure 1A: ((22), page 7:15-16) or Figure 2A: the channel in chip 118 that extends from 176, which corresponds to 22 in Figure 1A)

sample injecting portion - (Figure 1A:(26) or Figure 2A:(130))

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (WO 00/54041 A1) ("Li").

Li discloses an analyzing method for analyzing a sample, comprising the steps of filling a migration buffer in a separating channel (page 8:9-26; page 9:9-18; page 13:1-4; and page 13:12-13);

introducing the sample into the separating channel from a sample injecting portion for an amount corresponding to a volume of a sample quantity control channel branching from the separating channel (page 9:3-8; page 13:1-12; and page 14:11-22); and

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applying a voltage between the sample injecting portion and an end of the separating channel away from the sample-injecting portion so that the sample is separated by electrophoresis (page 8:1-8; page 9:17-18; page 12:13-19; and page 14:11-22).

Note:

separation channel - (Figure 1A: ((22), page 7:15-16) or Figure 2A: the channel in chip 118 that extends from 176, which corresponds to 22 in Figure 1A)

sample injecting portion - (Figure 1A:(26) or Figure 2A:(130)).

Li does disclose immersing the sample injecting portion into the sample (see Figures 1A and 2A) and applying voltage ((page 8:1-8; page 9:17-18; page 12:13-19; and page 14:11-22).

Li directly or implicitly discloses opening and closing various closing mechanisms during the filling of the migration buffer and the sample injection. See page 12:1-16. For example, if valve 44 is taken to be the first closing mechanism it is implicitly closed during the filling of the migration buffer since it is stated to be opened after the buffer has been loaded (page 12:7-9). If valve 52 is taken to be the second closing mechanism it is implicit open during the sample injecting since it is closed after the sample loading is complete (page 12:11-13). As for having the second closing mechanism closed during the filling of the migration buffer Li is silent. It would have been obvious to one with ordinary skill in the art at the time of the invention to also have the second closing mechanism closed during the filling of the migration buffer because this will help prevent migration buffer from entering the sample-injecting portion. If

migration buffer enters the sample injecting portion it will later have to be removed so that sample can be directed to the separation channel.

Allowable Subject Matter

7. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 3 requires the base member to include a lower surface from which the projection projects. As seen from Figures 2B and 2C the projection projects from an *upper* surface of the base member, that is, from the *same* surface on which the opening of the other end of the separating channel is located and on which an opening for one end of the sample quantity control channel is located. To have the projection project from the bottom of the base member would require significant structural modification of the base member. As seen if Figure 1C, for example, the top of the base member has been especially configured with pneumatic interfaces 76 and 80 and seals 78 and 82 for receiving all inflow and

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out-flow means. The channels have been etched into the bottom layer of the base member (page 9:19 – page 10:13)

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Nogueroles
Primary Examiner
AU 1753
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